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No More Imports: Seventh Circuit Decision in *United States v. Genendo* is an Expensive Pill for American Consumers to Swallow

Nicole L. Little
IIT Chicago-Kent College of Law

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BY NICOLE L. LITTLE*

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INTRODUCTION

Every day in the United States approximately fifty percent of adult consumers take at least one prescription drug.[1] In 2005, American consumers spent over 200 billion dollars on prescription drugs,[2] a number that is projected to rise to almost 500 billion by 2016.[3] As the amount of money American consumers spend on drugs rises, more American consumers struggle to pay for those drugs they need on a daily basis. Meanwhile, across the border in Canada, consumers pay up to forty percent less for the same drugs.[4] The same

* J.D. candidate, May 2008, Chicago-Kent College of Law, Illinois Institute of Technology, Certificate in Intellectual Property; B.S.E. Chemical Engineering, May 2005, University of Michigan, Ann Arbor.

[1] KAISER FAMILY FOUND., KAISER HEALTH POLL REPORT: PRESCRIPTION DRUG USE 1 (Feb. 2005), available at http://www.kff.org/healthpollreport/feb_2005/1.cfm.

[2] KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS FACT SHEET: MAY 2007 UPDATE 1 (2007), available at http://www.kff.org/rxdrugs/upload/3057_06.pdf.

[3] KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS FACT SHEET: MAY 2007 UPDATE 4 (2007), available at http://www.kff.org/rxdrugs/upload/3057_06.pdf.

[4] Donald L. Barlett and James B. Steele, *Why We Pay So Much For Drugs*, TIME, Feb. 2, 2004, at 1, *available at* http://www.time.com/time/magazine/article/0,9171,1101040202-581399,00.html.

is true for the cost of drugs in many other countries throughout the world.[5] Amid American consumers' battle to pay for their drugs, profits are soaring for pharmaceutical companies. For instance, in 2006, Pfizer reported $19.3 billion in profits,[6] Merck reported $4.4 billion in profits,[7] and Abbott Laboratories reported $1.7 billion in profits.[8] Many critics argue that the pharmaceutical companies are indifferent to American consumers' financial struggle to pay for their drugs, putting their own profits before the public's needs.[9] Yet, the research and development of pharmaceutical companies has yielded countless drugs upon which the public has come to depend.

The public has pressured Congress to follow the lead of other countries to help make drug prices more affordable for American consumers.[10] Many countries outside of the United States regulate

[5] Mike Adams, *28 Senators Vote to Maintain Big Pharma Monopoly Over U.S. Consumers; Republicans Oppose Free-Trade for Medicine*, NEWSTARGET.COM, May 7, 2007, http://www.newstarget.com/z021831.html (last visited Dec. 9, 2007) (claiming Canadians, Europeans and Mexicans pay from one-half to one-tenth the price that American consumers pay for their prescription drugs). *See also* Gardiner Harris, *The Nation: Prescriptions Filled; If Americans Want to Pay Less for Drugs, They Will*, THE NEW YORK TIMES, Nov. 16, 2003.

[6] PFIZER, PFIZER FINANCIAL REPORT 1 (2006), http://www.pfizer.com/investors/financial_reports/financial_report_2006.jsp (select "Financial Summary" from drop down menu).

[7] MERCK, UNITED STATES SECURITIES AND EXCHANGE COMMISSION FORM 10-K 117 (2007), http://www.merck.com/finance/proxy/2006_form_10-k.pdf.

[8] ABBOTT, ABBOTT 2006 ANNUAL REPORT 44 (2006), http://www.abbott.com/static/content/microsite/annual_report/2006/support_files/abbott_ar06_financial.pdf.

[9] Mike Hall, *What Drug Companies Aren't Telling YOU*, America@work, May 2003, http://www.aflcio.org/aboutus/thisistheaflcio/publications/magazine/0503_bigfix.cfm; *Cf.* MASSPIRG, *Prescription Action Litigation Project*, http://masspirg.org/health-care/safe-amp-affordable-drugs/prescription-action-litigation-project (discussing class action lawsuit against major pharmaceutical companies for price gouging).

[10] *See, e.g.*, H.R. 194, 110th Cong. (2007) (proposing tax credits for persons of "retirement" age for their prescription drugs); Prescription Drug Affordability Act of 2006, H.R. 4706, 109th Cong. (2006) (proposing depriving prescription drug manufacturers of certain tax deductions in an effort to lower drug prices); Prescription Drug Affordability Act of 2005, H.R. 563, 108th Cong. (2005) (proposing that the Secretary of Health and Human Services negotiate the lowest

their drug prices in one of three ways: (1) directly by price controls; (2) indirectly by reimbursement limits for social insurance used by their citizens; or (3) indirectly by profit controls.[11] Pharmaceutical companies are forced to comply with these drug regulations, resulting in their brand name drugs being sold abroad at outwardly reduced prices.[12]

Although Congress has shown an effort to consider some of these foreign cost-cutting methods, a large-scale change has not yet happened.[13] In the meantime, some American consumers have taken it upon themselves to engage in potentially dangerous and illegal cost-cutting measures. Some consumers report that they skip doses to make a prescription last longer or simply do not fill a prescription that they may need because of its cost.[14] Other consumers have turned to seemingly legitimate online pharmacies that tout brand name drugs at a highly reduced cost,[15] while still other consumers cross the border and buy prescription drugs in Canada or Mexico.[16]

Recognizing the drug industry's huge earnings and the public's increasing demand for low-cost prescription drugs, creative entrepreneurs have explored ways to enter the lucrative prescription drug market. One way these entrepreneurs become involved is by

possible pricing for Medicare beneficiaries and provide waivers to allow importation of prescription drugs from Canada).

[11] Patricia M. Danzon, *Making Sense of Drug Prices*, REGULATION, Spring 2000, 56, *available at* http://www.cato.org/pubs/regulation/regv23n1/danzon.pdf.

[12] *Id.*

[13] *See supra* note 8 and accompanying text.

[14] Patricia Barry, *Chasing Drugs: Many Readers Take Drastic Steps to Get Prescription Medicine*, AARP BULLETIN, October, 2003, http://www.aarp.org/bulletin/prescription/Articles/a2003-09-29-chasing_drugs.html.

[15] *Id.*; *see also* Michelle Meadows, *Saving Money on Prescription Drugs*, FDA Consumer, Sept.–Oct., 2005, *available at* http://www.fda.gov/fdac/features/2005/505_save.html.

[16] Barlett, *supra* note 4, at 1. *See also* HHS TASK FORCE, REPORT ON PRESCRIPTION DRUG IMPORTATION IX (2004), *available at* http://www.hhs.gov/importtaskforce/Report1220.pdf.

importing substandard or counterfeit drugs.[17] A second way is by purchasing brand name drugs manufactured abroad and importing them into the United States, a practice known as parallel imports.[18] This practice is theoretically legal under U.S. law because it is only unlawful to re-import drugs originally manufactured in the United States but shipped for sale abroad.[19] Genendo Pharmaceutical, N.V. ("Genendo"), a corporation based in the Netherlands, used this latter method in its course of business.[20] However, in 2003, when Genendo attempted to import a shipment of Lipitor manufactured and packaged abroad by Pfizer ("the imported Lipitor"), the government seized the drugs at the border, and sought their condemnation as unapproved new drugs.[21] The district court ruled in favor of the government on all counts.[22]

On appeal to the Seventh Circuit, the court was presented with a question of statutory interpretation of 21 U.S.C. §§ 353 and 355, and

[17] Calvert et al., *Factory for Fake Prescription Drugs*, THE SUNDAY TIMES (U.K.), Sept. 23, 2007, at Insight, *available at* http://www.timesonline.co.uk/tol/news/uk/health/article2511583.ece.

[18] United States v. 1500 90-Tablet Bottles, 384 F. Supp. 2d 1205, 1207 (N.D. Ill. 2005), *aff'd sub nom.* United States v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. 2007). *See also* Press Release, Genendo Pharmaceutical, NV, Trial Challenging the FDA's Pharmaceutical Importation Ban to Begin May 2nd, (Apr. 28, 2005), *available at* http://www.prnewswire.co.uk/cgi/news/release?id=145004. Parallel imports are genuine products (as opposed to counterfeit) that come from an area where the products are sold at discounted prices, in comparison to where the products will be imported (here, the U.S.).

[19] 21 U.S.C. § 353 (2006).

[20] *1500 90-Tablet Bottles*, 384 F. Supp. 2d at 1209.

[21] *Id*. at 1211. The process of seizure is based upon 21 U.S.C. § 334 (2006). Under the FDA's Regulatory Procedures, the United States files a Complaint for Forfeiture, directs the United States Marshal to seize the article in contention, and requests the court to condemn the article and declare forfeiture for violation of the law. FDA, REGULATORY PROCEDURES MANUAL, at 6-1 (2007), available at http://www.fda.gov/ora/compliance_ref/rpm/. Seizing an article may be accomplished by either taking physical possession or placing in constructive custody of the court. *Id*. A condemned article is one in violation of the law. *Id*. Condemned articles may be disposed of in a variety of ways, including constructive destruction, sale, conversion or destruction. *Id*. at 6-1-11.

[22] *Id*. at 1219.

the corresponding Food and Drug Administration ("the FDA") regulation.[23] In deciding this issue, the Seventh Circuit followed the FDA's proposed statutory interpretation.[24] While the Seventh Circuit's decision resulted in the correct outcome on the set of facts before it, the court's interpretation limits the scope of the provision. The practical effect of the decision reduces the potential opportunity for the importation of otherwise safe drugs and thus reduces the potential benefits the statute represented to the drug-consuming population in the United States. However, at the same time, the Seventh Circuit's decision may generate more attention and cause the import restrictions on prescriptions drugs to be investigated in a new light.

This article will examine and explore what the repercussions of the *Genendo* decision are for the future of drug importation. Part I provides the background of the case. Part II introduces the Federal Food, Drug and Cosmetic Act ("the FDCA") and the sections relevant to *Genendo*. Part III examines the district court decision and Part IV explains the Seventh Circuit's decision. Part V analyzes the Seventh Circuit's approach, and Part VI discusses the broader policy and practical implications of the Seventh Circuit's decision.

I. *UNITED STATES V. GENENDO*

A. Factual Background

Genendo is a corporation headquartered in the Netherlands, which purchases, trades and sells pharmaceuticals.[25] As part of its business, Genendo imports drugs into the United States that were both manufactured abroad and intended for distribution abroad.[26] At the heart of the issue in this case is Lipitor manufactured by Pfizer in

[23] United States v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. 2007).

[24] *Id.* at 962–63.

[25] United States v. 1500 90-Tablet Bottles, 384 F. Supp. 2d 1205, 1209 (N.D. Ill. 2005), *aff'd sub nom.* United States v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. 2007).

[26] *Id.*

Ireland,[27] and bought by Genendo in Argentina.[28] Genendo planned to import the Lipitor into the United States to Phil & Kathy's, an FDA-approved repackaging and labeling facility[29] located in Illinois.[30] Pursuant to a written agreement between Phil & Kathy's and Genendo, Phil & Kathy's would then repack and relabel the Lipitor.[31]

In September and October of 2003, Genendo sent letters to the U.S. Attorney's Office alerting the government of its plan to import the Lipitor to Phil & Kathy's.[32] Prior to these letters, Genendo unsuccessfully filed a declaratory judgment action to clarify its rights to import the Lipitor.[33] Genendo subsequently went forward with the importation of the Lipitor, but, on December 16, 2003, the government seized the Lipitor on its way to Phil & Kathy's.[34]

Pfizer received an FDA-approved new drug application ("NDA") for Lipitor.[35] Under that NDA, Lipitor to be sold in the U.S. must be manufactured in Loughbeg, Ireland or Vega Baja, Puerto Rico and must be packaged in Freiburg, Germany, or Vega Baja, Puerto Rico.[36] Additionally, the NDA specifies that the labeling for Lipitor must be in English, and its expiration period is two years from the manufacture date.[37]

The imported Lipitor was manufactured in the NDA-approved facility in Loughbeg, Ireland but was packaged in Guarulhos SP,

[27] *Id*. at 1212.
[28] *Id*. at 1210.
[29] *Id*. at 1213.
[30] *Id*. at 1212.
[31] *Id*. The Agreement also covered Zocor imported by Genendo that was also in dispute. *Id*. at 1207. However, the Zocor ruling was not appealed and will not be addressed in this article.
[32] *Id*. at 1210.
[33] *Id*. at 1209–10. Genendo sought a declaration that importing the Lipitor was authorized under the FDCA; however, the district court granted a motion brought by the United States to dismiss the action because there was not an agency action ripe for review. *Id*. at 1210.
[34] *Id*.
[35] *Id*. at 1210.
[36] *Id*. at 1212.
[37] *Id*.

Brazil.[38] Additionally, the imported Lipitor bore labels in Portuguese that displayed expiration dates three years from the manufacture date.[39]

B. The Procedural Posture

After seizing the imported Lipitor, the government brought suit against Genendo[40] seeking condemnation of the imported Lipitor as both an unapproved new drug and as a misbranded drug.[41] The government also sought a permanent injunction to prohibit Genendo from violating the FDCA with similar imports in the future.[42] Genendo responded that the imported Lipitor was not an unapproved new drug or a mislabeled drug because it fell within the exemption of 21 U.S.C. § 353(a) and 21 C.F.R. § 201.150.[43]

The district court found for the government on all counts, resulting in the condemnation of the imported Lipitor and the entry of a permanent injunction against Genendo.[44] Genendo appealed the district court's decision to the Seventh Circuit.[45] The issue presented to the Seventh Circuit was whether the imported Lipitor was an unapproved new drug or whether the imported Lipitor was exempt from the NDA provisions under § 353.[46]

Before analyzing the district court and Seventh Circuit decisions, more explanation of the FDCA and its relevant provisions is necessary.

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[38] *Id*. The Brazil facility is not listed as an approved facility on the NDA and has not been inspected by the FDA. *Id*.

[39] *Id*. at 1210–11.

[40] The United States also sued Phil & Kathy's, but the parties entered into a consent decree settling their claims. *Id*. at 1212.

[41] *Id*. at 1207.

[42] *Id*.

[43] *Id*. As explained in more detail, *infra* at II.B., § 353(a) and § 201.150 together state an exemption that drugs in transit to and held at a repackaging facility do not have to comply with certain labeling and packaging requirements of the FDCA.

[44] *Id*. at 1219. The analysis of the district court's decision is discussed *infra* at III.

[45] United States v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. 2007).

[46] *Id*. at 962.

II. THE FEDERAL FOOD, DRUG AND COSMETIC ACT

A. Brief Overview of the FDCA

The first Food and Drugs Act, passed in 1906, prohibited the introduction of misbranded and adulterated foods, drinks and drugs into interstate commerce.[47] The 1906 Act was repealed in 1938 and replaced with the enactment of the current FDCA.[48] Over the years, the FDCA has been amended over twenty times, and it currently regulates a wide range of products, including foods, dietary supplements, drugs, medical devices, and cosmetics.[49] The FDA is the government agency charged with enforcing the FDCA.[50]

The FDCA has two main goals underlying its enactment: safety and disclosure. The Supreme Court recently restated this first goal, stating that a "fundamental precept of the FDCA is that any product regulated by the FDA – but not banned – must be safe for its intended use."[51] The second goal, disclosure, is evident through the provisions demanding truthful information used in labels. This goal traces back to the 1906 Act, which was partially enacted to prevent the use of "cure-

[47] FDA: MILESTONES IN U.S. FOOD AND DRUG LAW HISTORY (1999), http://www.fda.gov/opacom/backgrounders/miles.html.

[48] Federal Food Drug And Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–397 (2004)).

[49] *See* 21 U.S.C. §§ 301–397.

[50] FDA, Laws Enforced by the FDA and Related Statutes, http://www.fda.gov/opacom/laws/#amendments (last visited Oct. 17, 2007). The FDA is a part of the Department of Health and Human Services (HHS). Food and Drug Administration, FDA Organization, http://www.fda.gov/opacom/7org.html (last visited Oct. 17, 2007). At the direction of Congress, the Secretary of HHS promulgates regulations. *See e.g.*, 21 C.F.R. § 201.150 (regulation promulgated in response to Congress' instruction in 21 U.S.C. § 353). The FDA then uses these regulations in its enforcement of the FDCA.

[51] Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 142 (2000); *See also* United States v. Dotterweich, 320 U.S. 277, 280 (1943) ("The purposes of [the FDCA] thus touch phases of the lives and health of people, which, in the circumstances of modern industrialism, are largely beyond self protection.").

all" claims for ineffective and often dangerous medicines.[52] These provisions are still found in the current FDCA through misbranding prohibitions and labeling requirements.[53]

B. The Relevant Sections of the FDCA

The FDCA has a broad coverage; however, only two of its provisions are pertinent to the discussion here—section 355 involving new drug applications ("NDAs") and § 353 involving exemptions for certain drugs under the FDCA. Also relevant is the regulation promulgated by the FDA in response to the mandate in § 353 from Congress, 21 C.F.R. § 201.150.[54] Each of these provisions will be discussed in turn.

In *Genendo*, the government asserted that the imported Lipitor was an unapproved new drug in violation of § 355(a).[55] This section is complex and details the various requirements a pharmaceutical company must meet to gain FDA approval to market a "new" drug. A new drug is one not yet "generally recognized among experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ."[56] Under § 355, an application for a new drug must be filed detailing, *inter alia*, the methods and facilities used for manufacturing, processing and packaging the drug.[57] When the FDA grants approval of an NDA, the

[52] FDA, MILESTONES IN U.S. FOOD AND DRUG LAW HISTORY (1999), http://www.fda.gov/opacom/backgrounders/miles.html.

[53] *See, e.g.*, 21 U.S.C. §§ 331(a), 352(a) (prohibiting introduction of misbranded drugs or drugs with false or misleading labels into interstate commerce, respectively); *see also* FDA, WHAT FDA REGULATES, http://www.fda.gov/comments/regs.html (last visited Oct. 17, 2007) (stating that the FDA "ensures that [the regulated products] are honestly, accurately and informatively represented to the public").

[54] 21 C.F.R. § 201.150 (1999) is often referred to as "the § 353 exemption." This designation will be used in the remainder of this article.

[55] United States v. Genendo Pharm., N.V., 485 F.3d 958, 960 (7th Cir. 2007).

[56] 21 U.S.C. § 321(p) (2006).

[57] *Id.* § 355(b)(1)(D).

drug may then be legally introduced into U.S. interstate commerce.[58] Pfizer submitted an NDA and obtained FDA approval for Lipitor; however, the imported Lipitor did not fully comply with that NDA.[59]

Despite the non-compliance of the imported Lipitor with the NDA, Genendo argued that the drugs could lawfully be put into interstate commerce because they fell within the exemption stated in § 353.[60] That statute states in pertinent part:

> (a) Regulations for goods to be processed, labeled, or repacked elsewhere. The Secretary is hereby directed to promulgate regulations exempting from *any* labeling or packaging requirement of this Act [21 USCS §§ 301 et seq.] drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act [21 USCS §§ 301 et seq.] upon removal from such processing, labeling, or repacking establishment.[61]

The government, however, argued that the imported Lipitor did not fall within the language of § 353; rather, the § 353 exemption promulgated by the FDA exempted Genendo from compliance with only the six packaging and labeling requirements listed in the § 353 exemption.[62] The § 353 exemption states in pertinent part:

> (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug which is, in accordance with the practice of the trade, to be processed,

[58] *Id.* § 355(a).

[59] *Genendo*, 485 F.3d at 960–61. The non-compliance of the imported Lipitor with the NDA was admitted by Genendo. *Id.* at 961.

[60] *Id.*

[61] 21 U.S.C. § 353(a) (2006) (emphasis added).

[62] *Genendo*, 485 F.3d at 962.

> labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) [21 U.S.C. § 351(b)] and 502 [21 U.S.C. § 352] (b), (d), (e), (f), and (g) of the act . . . . [63]

The six subsections listed in the § 353 exemption generally set forth conditions under which a drug shall be considered adulterated or misbranded.[64] The statutory interpretation of § 353, and its corresponding regulation, are at the center of the dispute in *Genendo*.

III. THE DISTRICT COURT PROCEEDINGS

The United States government sought condemnation of the imported Lipitor on various grounds: first, as an adulterated drug under 21 U.S.C. § 351(a)(2)(B) that did not comply with the FDA's continuing Good Manufacturing Practices ("cGMP");[65] second, as a

[63] 21 C.F.R. § 201.150(a) (1999). Since this regulation was written, § 502(d) has been repealed. Food and Drug Modernization Act of 1997, Pub. L. No. 105–115, § 126, 111 Stat. 2296, 2327 (1997).

[64] Specifically, § 351(b) states that a drug shall be considered adulterated "[i]f it purports to be or is represented as a drug . . . and its strength differs from, or its quality or purity falls below, the standard set forth in [an official] compendium. . . ." 21 U.S.C. § 351(b). Sections 352(b), (e), (f) and (g) refer to package form and contents of the label, designation of drugs by established names, directions for use and warnings on the label, and representations as recognized drugs.

[65] Amended Verified Complaint for Forfeiture and Permanent Injunction ¶¶ 31–40, United States v. 1500 90-Tablet Bottles, 384 F. Supp. 2d 1205 (N.D. Ill. 2005) (No. 03 C 6495), 2003 WL 23799518. 21 U.S.C. § 351(a)(2)(B) states that a drug shall be considered adulterated "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act [21 USCS §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

misbranded drug under 21 U.S.C. § 352(c) that did not bear labels in the English language;[66] third, as a misbranded drug under 21 U.S.C. § 352(f) that did not bear adequate directions for use;[67] and finally as an unapproved new drug that was manufactured abroad and not manufactured, processed and packaged (including its labeling) and held in full compliance with the NDA for Lipitor.[68] Specifically, the government argued that any drug that does not display the *exact* label approved in the NDA is an unapproved new drug.[69] The government also alleged that no exemptions promulgated by the FDA applied to the drugs to excuse Genendo from compliance with the English-language and directions for use labeling requirements.[70]

Genendo asserted several affirmative defenses in response: (1) the drugs were not misbranded;[71] (2) the drugs were not new;[72] (3) Genendo's activities did not fall within § 331(k) or § 351(a)(2)(B);[73] (4) the English label and adequate directions for use label requirements did not apply to Genendo because Genendo does not label the drugs—those requirements only apply to Phil & Kathy's for

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The actual violation alleged is of 21 U.S.C. §331(k), which prohibits any person from causing the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

[66] Amended Verified Complaint for Forfeiture and Permanent Injunction, *supra* note 65, ¶¶ 41–45. 21 U.S.C. § 352 and its implementing regulations, such as 21 C.F.R. § 201.15, set forth detailed requirements for drug labels, including that the information appear "prominently and conspicuously" in English so that an ordinary person buying and using the drug can read and understand the label.

[67] Amended Verified Complaint for Forfeiture and Permanent Injunction, *supra* note 65 ¶¶ 46–48.

[68] *Id*. ¶¶ 49–52.

[69] *Id*. ¶ 50.

[70] *Id*. ¶¶ 44, 47.

[71] Genendo's Verified Answer and Affirmative Defenses to the Amended Verified Complaint for Forfeiture and Permanent Injunction, United States v. 1500 90-Tablet Bottles, 384 F. Supp. 2d 1205 (N.D. Ill. 2005) (No. 03 C 6495), 2004 WL 2174705 (first and sixth affirmative defenses).

[72] *Id*. (first and fifth affirmative defenses).

[73] *Id*. (third affirmative defense).

the *relabeled* product, which the government cannot allege has been violated since the drugs were seized prior to relabeling;[74] (5) the FDA has effectively prohibited parallel drug importation and thus exceeded its statutory and regulatory authority.[75]

The district court proceedings focused on whether the § 353 exemption excused Genendo from fully complying with the NDA for Lipitor. Siding with the government, the district court held that "a new drug's failure to be manufactured and/or packaged according to the exact requirements of an FDA- approved NDA are not exempted by § 353(a) of the Act."[76] The district court based its holding upon its reading of the FDCA provisions and Seventh Circuit precedent.[77] The district court quoted *United States v. Baxter Healthcare Corp.* for the proposition that "the detailed requirements of the new drug approval process of § 355 reflect 'a Congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs.'"[78] The district court also relied upon *Baxter* for the rule that a drug must comply with *all* requirements of the NDA in order to be properly introduced into interstate commerce.[79] The district court also found that Genendo's proposed reading of the § 353 exemption would eviscerate the protections of the new drug approval process.[80] The court "harmonized" the § 353 exemption with the new drug approval process by giving "packaging" and "labeling" their general meaning throughout most of the act, but giving these terms special meanings within the NDA provisions.[81] Packaging and labeling generally refer to "a type of packaging with descriptive terms" where

[74] *Id*. (fourth affirmative defense).

[75] *Id*. (seventh affirmative defense). Genendo also alleged that it did not own, import or control the vast majority of the drugs seized by the FDA. *Id*. (second affirmative defense). This defense will not be addressed in this article.

[76] *1500 90-Tablet Bottles*, 384 F. Supp. 2d at 1214.

[77] United States v. Baxter Healthcare Corp., 901 F.2d 1401 (7th Cir. 1990).

[78] *1500 90-Tablet Bottles*, 384 F. Supp. 2d at 1215 (citing *Baxter*, 901 F.2d at 1411).

[79] *Id*. The Seventh Circuit in *Baxter* did not state such a proposition. *See Baxter*, 901 F.2d at 1411.

[80] *1500 90-Tablet Bottles*, 384 F. Supp. 2d at 1216.

[81] *Id*. at 1217.

within the NDA provisions, it takes on the special and more specific meaning, which includes the "'methods used in, and the facilities and controls used for, the . . . processing and packing of such drug.'"[82] According to the district court, this interpretation harmonized the two seemingly conflicting provisions while still honoring the sense and purpose of each.[83]

Finally, the district court rejected Genendo's argument that *Kaybel*[84] should affect the court's decision. The court distinguished this case because the repackaged drugs in *Kaybel* were compliant with the NDA, unlike the imported Lipitor in the present case.[85] In the end, the district court ruled that the imported Lipitor was subject to condemnation as an unapproved new drug and permanently enjoined Genendo from introducing any other unapproved new drugs into interstate commerce.[86]

IV. THE SEVENTH CIRCUIT DECISION

Genendo appealed the district court's decision to the Seventh Circuit.[87] The only issue on appeal was whether the imported Lipitor was a new drug.[88] The Seventh Circuit framed the question as whether § 353(a) exempted Genendo from compliance with the NDA requirements, which as a question of statutory interpretation was subject to *de novo* review.[89] The court thus first had to confront the question of the level of deference to give the FDA's interpretation of § 353.[90]

[82] *Id*. (quoting 21 U.S.C. § 355(b)(1)(D)).
[83] *Id*.
[84] United States v. Kaybel, 430 F.2d 1346 (3d Cir. 1970).
[85] *1500 90-Tablet Bottles*, 384 F. Supp. 2d at 1217–18.
[86] *Id*. at 1218–19.
[87] The case proceeded on appeal under the name United States v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. May 10, 2007).
[88] *Id*. at 962.
[89] *Id*.
[90] *Id*.

Genendo argued that the statutory language and Congressional intent were clear and that under *Chevron*[91] the court must give effect to that intent and not defer to the FDA's interpretation of the statute.[92] Genendo argued that the language of § 353 clearly states that "as long as the imported, properly manufactured drug is *en route* to or *at* the repacker, it is exempt from any packaging and labeling requirements."[93] As proof of congressional intent, Genendo relied upon a statement by Senator Copeland in which he stated that substances "need not be labeled, and so forth, until after they are ready actually to be sent on to the ultimate consumer."[94] Thus, since the imported Lipitor was on its way to Phil & Kathy's, it could not be an unapproved new drug or misbranded due to its non-English labels, allegedly inadequate directions for use, or longer expiration date periods, since no labels were necessary at all.[95] According to Genendo, these deficiencies in the labels were all to be corrected at Phil & Kathy's, pursuant to the written 201.150 Agreement between them, and the labeling and packaging requirements only applied once the drugs were outbound from Phil & Kathy's.[96]

[91] Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984). Under *Chevron*'s analysis, a court must first look to see if Congress has spoken to the precise issue. *Id.* at 842. If they have, that is the end of the inquiry, as both the agency and the court must adhere to that unambiguous intent. *Id.* at 842–43. If, however, Congress has not spoken on the issue or the intent is ambiguous, the court must ask whether the agency's construction of the statute is a permissible one. *Id.* at 843. The legislative regulation that Congress has left to the agency must be given deference unless its construction is arbitrary, capricious or manifestly contrary to the statute. *Id.* at 843–44. The deference that the court gives to a federal agency in this situation is now known as "*Chevron* deference." *See, e.g.*, Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Serv., 545 U.S. 967, 982 (2005) (using the term "*Chevron* deference"); United States v. Haggar Apparel Co., 526 U.S. 380, 389 (1999) (referring to the "usual rule of *Chevron* deference"); Sullivan v. Stroop, 496 U.S. 478, 495 (1990) (using the term "*Chevron* deference").

[92] Brief of Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *16–17.

[93] *Id.* at *17 (emphasis in original).

[94] *Id.* at *13–14 (quoting Federal Food, Drug and Cosmetic Act, A Statement of its Legislative Record, 74th Cong. 363 (1938 *reprinted* 1987)).

[95] *Id.* at *24.

[96] *Id.* at *28.

The government argued that the district court decision was correct. First, the government stated that the FDA's interpretation of § 353 through its regulation was entitled to great deference under *Chevron*.[97] Without much explanation, the government stated that the statutory language is ambiguous, and since the FDA was charged with making a regulation that carries the force of the law, its interpretation should be respected.[98] The government echoed much of the district court's decision but went on to state that if Congress had intended to exempt all of the NDA requirements under § 353, they could have written that exemption into the statute themselves.[99] The government also disparaged Genendo's reliance upon Senator Copeland's statements because his statement was only useful to show that the statute's language was now *requiring* the FDA to promulgate a regulation rather than *authorizing* the FDA to do so.[100]

The Seventh Circuit held that the FDA's interpretation deserved *Chevron* deference.[101] In doing so, the court first asked whether Congress had spoken to the precise issue.[102] The court stated that "[Section] 353 simply directs 'the Secretary' to promulgate regulations exempting drugs en route to a repackager from labeling packaging requirements; it does not itself provide for a complete exemption."[103] The court relied on *Arner Co. v. United States*[104] to support the proposition that Congress would have stated the exemption on its own rather than provide for a regulation to formulate one.[105] The court rejected Genendo's argument that Congress had spoken to the issue by turning to the regulation promulgated by the FDA:

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[97] Brief for the Appellee United States, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (7th Cir. 2007) (No. 03 C 6495), 2006 WL 4820664, at *21.

[98] *Id.* (citing United States v. Mead Corp., 533 U.S. 218, 229 (2001)).

[99] *Id.* at *24.

[100] *Id.* at *25. The government contends that there is nothing in the legislative history to suggest that Congress intended to exempt drugs from the new drug approval requirements. *Id.* at *24–25.

[101] *Genendo*, 485 F.3d at 962.

[102] *Id.* at 962.

[103] *Id.* at 962–63.

[104] 142 F.2d 730 (1st Cir. 1944).

[105] *Genendo*, 485 F.3d at 963.

> The problem with Genendo's argument is that it largely ignores the fact that the promulgated regulation, § 201.150, sets forth specific labeling and packaging requirements from which drugs being repackaged are exempt. The particular sections of the FDCA referenced in § 201.150 relate to [specific] requirement[s about the packaging] . . . . Section 201.150 thus does not exempt drugs in transit to or at a repackager from all labeling and packaging requirements in the Act, as Genendo suggests--simply those listed.
>
> Thus the statute is not so crystal clear as Genendo insists.[106]

The court then turned to an investigation of the meaning of the word "any" within § 353. The statutory language reads in pertinent part:

> The Secretary is hereby directed to promulgate regulations exempting from *any* labeling or packaging requirement of this Act drugs . . . which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs . . . are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.[107]

The court turned first to a dictionary for the meaning of "any," noting that the first definition is "'one, a, an, or some'" while the fourth definition is "all."[108] The court then states:

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[106] *Id*.

[107] 21 U.S.C. § 353(a) (2000) (emphasis added).

[108] *Genendo*, 485 F.3d at 963 (citing WEBSTER'S UNABRIDGED THIRD DICTIONARY OF THE ENGLISH LANGUAGE 96 (2d ed. 2001)).

> Although the statute could be read as if any meant all . . . it could also be read to [mean] *some* . . . . Given that § 201.150 exempts drugs in transit only from specified labeling and packaging requirements, the Secretary apparently understood it to mean the latter.[109]

In a footnote, the court addressed a recently decided Supreme Court case cited by Genendo in which the Supreme Court construed "any" air pollutant to mean "all" air pollutants.[110] The court distinguished this precedent on the basis that the Supreme Court was construing language in the Clean Air Act, which contained a "sweeping" definition of air pollutant, whereas the exemption in § 353 does not contain a similar sweeping definition or otherwise indicate that "any" should be so construed.[111] The court concludes that the Supreme Court's interpretation in *Massachusetts* was a specific case where "any" meant "all" but that the holding was not so broad as to mandate that this definition be applied in every other case.[112]

The court concluded that both Genendo's and the FDA's readings of the statute were possible interpretations, and thus that there was enough ambiguity in the statute such that the court should defer to the FDA's chosen interpretation, provided the interpretation was not arbitrary, capricious or manifestly contrary to the statute.[113] The court found that this standard was met and that the interpretation was in line with the court's "observation in *Baxter* that the new drug approval process 'illustrates a congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs at issue.'"[114] The court noted that under Genendo's interpretation, drugs not packaged in conformity with the

[109] *Id*.

[110] *Id*. at 963 n.3. The Supreme Court decision being discussed is Massachusetts v. EPA, 127 S. Ct. 1438 (2007).

[111] *Genendo*, 485 F.3d at 963 n.3.

[112] *Id*.

[113] *Id*. at 963–64.

[114] *Id*. at 964 (citing United States v. Baxter Healthcare Corp., 901 F.2d 1401, 1411 (7th Cir. 1990)).

NDA, such as the imported Lipitor packaged in Brazil, but subsequently repackaged under the § 353 exemption successfully avoid the NDA's requirement that original packaging occur in an approved facility.[115] The court stated that "If such a result were intended, we believe that the statute and accompanying regulation would say so explicitly."[116]

Genendo argued that the Third Circuit's holding in *United States v. Kaybel*[117] mandated a different result. In *Kaybel*, the court held that a wholesale distributor did not introduce an unapproved new drug into interstate commerce when it repackaged the drug without obtaining a new drug application in its own name first.[118] The court distinguished *Kaybel* on two grounds. First, *Kaybel* did not deal directly with § 353.[119] Second, the facts of *Kaybel* involved the repackaging of a drug that was compliant with the NDA in all respects.[120] The court emphasized that *Kaybel*'s rationale was that other provisions exist to protect drugs from being contaminated by repackagers, and this rationale did not apply to the facts before it.[121]

V. ANALYSIS OF THE SEVENTH CIRCUIT DECISION

Based on the set of facts before it, the Seventh Circuit correctly decided *Genendo*. The court's reasoning, however, is problematic. The court began by noting that the issue before it was one of statutory interpretation—whether Genendo was exempt under § 353 from complying with the NDA provisions—which subjected the district court's holding to *de novo* review.[122] This led into the main issue of what level of deference the court should give the FDA's interpretation

[115] *Id*.
[116] *Id*.
[117] 430 F.2d 1346 (3d Cir. 1970).
[118] *Id*. at 1347. The drug manufacturer, Searle, obtained an NDA in its own name for the drug which was still in effect when the defendant repackaged the drug into smaller bottles for sale. *Id*.
[119] *Genendo*, 485 F.3d at 965.
[120] *Id*.
[121] *Id*.
[122] *Genendo*, 485 F.3d at 962.

of § 353(a).[123] The court determined that the statute is ambiguous and that it must defer to the reasonableness of the FDA's interpretation.[124] The overarching question is how the court arrived at its conclusion that the statute is ambiguous. The court's analysis would be sounder if they examined whether Congress spoke to the issue, steered away from reliance upon dictionary definitions, and considered the legislative history and other sections of the FDCA in its investigation.

A. The Chevron *Analysis*

1. The Vague Intent of Congress

Under the first step of the *Chevron*[125] analysis:

> First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute. [126]

The court stated that Genendo believed Congress had spoken directly to the issue with § 353 by using the phrase "any labeling and

[123] *Id*. at 962.
[124] *Id*. at 964.
[125] Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).
[126] *Id*. at 842–43 (footnotes omitted).

packaging requirement."[127] The court found this argument problematic because the § 353 exemption lists specific labeling and packaging requirements with which a repackaged drug does not have to comply.[128] The court concluded that the § 353 exemption "thus does *not* exempt drugs in transit to or at a repackager from *all* labeling and packaging requirements in the Act, as Genendo suggests—simply those listed."[129] On this point, the court is correct. In its brief, Genendo stated that as a result of the language Congress used in § 353, the FDA had "no option but to promulgate a regulation that exempted drugs en route to and while being held by a repacker and labeler from *all* of the labeling and packaging requirements of the Act. The FDA 'performed this prescribed duty' when it promulgated [the § 353 exemption]."[130] However, it is hard to see how Genendo can argue the FDA correctly performed its duty by exempting all packaging and labeling requirements when instead its regulation specifically lists only six of those requirements.[131]

Despite this flaw in Genendo's argument, the court nevertheless missed the most important part of the argument: just because the regulation lists six specific packaging and labeling exemptions does not mean Congress failed to speak directly to the issue. There is always the possibility that the regulation is improper and has ignored the direct mandate of Congress. Judicial review of such administrative constructions is in place to prevent such occurrences. A court is the final authority on statutory construction and it must reject any administrative construction that is inconsistent with "clear congressional intent. If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect."[132]

[127] *Genendo*, 485 F.3d at 962.

[128] *Id*. at 963.

[129] *Id*.

[130] Brief of Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *14.

[131] The six requirements listed as exempted are sections 501(b) and 502 (b), (d), (e), (f), and (g). 21 C.F.R. § 201.150(a).

[132] Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 n.9 (1984) (citations omitted); *see also* Fed. Election Comm'n v. Democratic

Here, the court only superficially investigated congressional intent. The only statutory interpretation tool the court consulted was a dictionary definition.[133] Relying on Webster's Unabridged Dictionary of the English Language, Second Edition, as its dictionary of choice, the court stated that "the first definition given for the word any is 'one, a, an, or some'" while, of course, "all" is not until the fourth definition.[134] By itself, this approach is questionable. How did the court determine that the Second Edition of Webster's Unabridged was the dictionary with the right definition? A cynical answer is that it was simply the dictionary sitting on the desk of the law clerk at the time.

However, a different Webster's Dictionary first defines "any" as "[o]ne, no matter which, of more than two" and provides "some, no matter how much or how little, how many, or what kind" as the second definition.[135] In the Oxford English Dictionary, the first definition of "any" is "[a]n indeterminative derivative of *one*, or rather its weakened adj. form . . . [i]ts primary use is in interrogative, hypothetical and conditional forms of speech" without regard to kind.[136] Oxford's second definition is "[w]ith a specially quantitative force = A quantity or number however great or small."[137] The American Heritage Dictionary's first definition of "any" is "[o]ne, some, every, *or all* without specification."[138] Thus, it would appear that if the court consulted any ("any" meaning "all" here) of these dictionaries, the court could have simply picked the dictionary with the most favorable definition.

If Congress had intended to exempt repackaged drugs from all packaging and labeling requirements, they could have expressly put

Senatorial Campaign Comm., 454 U.S. 27, 32 (1981) (stating that a court must reject any administrative construction that is inconsistent with Congress' statutory mandate).

[133] *Genendo*, 485 F.3d at 963.

[134] *Id*.

[135] WEBSTER'S NEW WORLD COLLEGE DICTIONARY 64 (4th ed. 2000).

[136] THE OXFORD ENGLISH DICTIONARY 538 (2d ed. 1989).

[137] *Id*. at 539.

[138] AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2000) (emphasis added).

that language into the statute, as the court implied.[139] However, the argument also swings the other way. Congress could have either used the word "some" in place of "any" in § 353 or defined "any" within § 353 if they did not mean to exempt the drugs from *all* labeling and packaging requirements. Congress did not do either of these.

Rather than solely relying upon a dictionary definition, the court could have consulted other sections and subsections of the FDCA for guidance. For example, the word "any" is used twenty-five times other than the disputed instance in § 353 alone.[140] A brief glance at these other uses of "any" demonstrates that "any" cannot mean "some" in every single use of the word. Nor can "any" mean "all" in each instance. This suggests that finding the right definition for this particular instance is likely not as easy as flipping open the dictionary and using the first definition. The word has to be read in context of both the specific section and the entire statute.

More importantly, the court could have consulted the legislative history of § 353. The entire FDCA went through many versions, resulting in various congressional reports and floor debates.[141] One such report notes that:

> Section 503 [21 U.S.C. § 353] prescribes exemptions from labeling requirements for drugs and devices similar to those provided for food when the articles are to be processed, labeled, or repacked at points other than their place of production and when, after the processing, labeling, or repacking they comply with the terms of the law . . . .[142]

In its brief, cited Senator Copeland, the sponsor of the FDCA, on the Senate floor:

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[139] *Genendo*, 485 F.3d at 962–63.

[140] *See* 21 U.S.C. § 353 (2000).

[141] HARRY A. TOULMIN, JR., A TREATISE ON THE LAW OF FOOD, DRUGS AND COSMETICS § 7 (1942).

[142] *Id*. at § 251 (citing H.R. Rep. No. 75-2139 (1938)).

> [P]erhaps the Senator did not know that on line 3 we have stricken out the word "authorized" and have provided that the Secretary shall be directed. The Secretary is directed to promulgate regulations exempting from labeling such articles as those to which the Senator has referred.
>
> I am satisfied that with this change, which was suggested by the Senator from Michigan [Mr. Vandenberg], directing the Secretary to take such action, we are not leaving the matter to anybody. *The Secretary must do what the Senator seeks to have done* when the substances covered by the provision are shipped in large quantities and are not sold to the consumer. *They need not be labeled, and so forth, until after they are ready actually to be sent on to the ultimate consumer*. So I feel that under subsection (1) the industry in which the Senator is interested is fully protected, in view of the fact that we have not given the Secretary any option in the matter, but he must perform this prescribed duty.[143]

Another Legislative statement shows the reasoning behind this prescribed duty: "This exemption is necessary to avoid unwarranted interference with certain legitimate commercial operations, such as the canning of food at branch canneries and delivery to a central plant for labeling, or the bulk shipment of crude drugs for processing and repacking before distribution to consumers."[144] A House Report also explained that, with respect to the food, "these exemptions will apply only where the interests of consumers will not be jeopardized."[145]

These congressional statements, when read together, demonstrate that it was the intent of Congress that the exemptions apply so that certain legitimate commercial operations would not be interfered with, so long as the consumer's interests would not be jeopardized. The legislative intent, demonstrated by these statements, was to protect the

[143] Brief of Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *13–*14 (emphasis in original).

[144] S. REP. NO. 73–493, at 9 (1934).

[145] H.R. REP. NO. 75-2139, at 6 (1938).

consumer. This legislative intent supports the ultimate result in *Genendo* and would give more credibility to the court's reasoning.

However, *Genendo* did not base its holding on this congressional intent. Rather, the court held that the statutory language was ambiguous enough to merit turning to the FDA's interpretation of the rule.[146]

2. The Reasonableness of Agencies

Once a court has determined that it will defer to an agency's interpretation, its holding is rarely disturbed because of the high arbitrary and capricious standard.[147] In *Genendo*, it would be hard to argue that the FDA's interpretation was arbitrary, capricious or manifestly contrary to the statute. The regulation only exempts the packaging and labeling requirements "that the package contain the name and address of the manufacturer or distributor, a statement of the quantity of the contents, the established name of the drug, active and inactive ingredients, and adequate warnings and directions for use."[148] This leaves in place other provisions mandating proper handling of drugs to ensure their safety. The court correctly points out that the interpretation appears to be "consistent with the public health concerns animating the new drug approval process and the FDCA as a whole."[149] It is important to keep in mind that the agency interpretation need not be the only permissible interpretation nor does it have to be the interpretation at which the court would have reached if construing the statute on its own.[150]

Accordingly, Genendo's interpretation raises an interesting question as to whether its interpretation would have been permissible had it been the position advanced by the FDA. Genendo claimed that exempting the imported Lipitor from all packaging and labeling

[146] *Genendo* 485 F.3d at 963–64.

[147] *See* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984).

[148] *Genendo*, 485 F.3d at 963.

[149] *Id.* at 964.

[150] *Chevron*, 467 U.S. at 843.

requirements did not put consumers at any risk because both § 353 and the § 353 exemption still contained a requirement that the drugs not be adulterated or misbranded.[151] Thus, any deviations from the NDA that occurred before the drugs were repackaged would still result in the drugs being properly seized as misbranded or adulterated.[152] The court in *Genendo* stated that "even assuming a flawless repackaging process at Phil & Kathy's . . . certain deviations from the NDA's requirements are never rectified despite the repackaging. Notably, the fact that the Lipitor was packaged at an unapproved facility in Brazil can never be brought into compliance with the NDA."[153] Genendo's response was that Congress and the FDA determined through § 353 and the § 353 exemption that the only NDA requirement that needed to be complied with when a drug is being imported is that it was manufactured in an NDA-approved, and thus FDA-approved, facility.[154] The result of this regulatory scheme would adequately safeguard consumers.[155]

If this were the FDA's interpretation and the government's argument before the court, the court would likely have to defer to it. "If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation."[156] If the FDA determined that consumers were adequately safeguarded by such a construction, then the interpretation would also be in line with the underlying purposes of the FDCA. Courts are typically viewed as unqualified to determine whether the agency's interpretation is correct. Instead courts must defer to the agency because their interpretation is considered reasonable.[157]

[151] *Genendo*, 485 F.3d at 964.

[152] *Id*.

[153] *Id*.

[154] Brief of Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *23.

[155] *Id*.

[156] Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843–44 (1984).

[157] *Id*. at 844.

2. Other Bumps in the Road: Distinguishing the Case Law

On the way to reaching the correct result, the court also had to face some case law that appeared to be on point. First, the court faced the Supreme Court's new decision in *Massachusetts v. EPA*,[158] in which the Supreme Court construed "any air pollutant" to mean "all" air pollutants.[159] While this decision would seem quite relevant, the *Genendo* court correctly disposed of this argument in a footnote. As discussed *infra*, the word "any" cannot be given a single meaning within § 353 itself. Thus, it is hard to imagine that the Supreme Court's interpretation of "any" in a completely different Act could be the definitive meaning of the word in § 353 as well.

The court also had to deal with the *Kaybel* case from the Third Circuit.[160] The *Kaybel* case is easily distinguishable from the facts at bar because the drugs in *Kaybel* were packaged at an NDA-approved facility.[161] In addition, neither § 353 nor the § 353 exemption are at issue in *Kaybel*.[162] Genendo's argument is that the *Kaybel* court's holding is that, "when a valid NDA is in place for the solid oral dosage form of a drug, deviations from the packaging and labeling listed on the NDA do not convert approved solid oral dosage forms of drugs into 'unapproved new drugs.'"[163] Genendo reiterated their version of this holding again as "packaging and labeling do not affect a drug's status as an approved 'new drug.'"[164] However, with these statements, Genendo repeatedly overstates the holding in *Kaybel*. The *Kaybel* court never stated that where a drug was packed is irrelevant to whether it is a "new drug." The *Kaybel* court, in fact, says very little in its short opinion. The Seventh Circuit correctly dismisses Kaybel as having very little applicability to the set of facts before it.

[158] Massachusetts v. EPA, 127 S. Ct. 1438 (2007).
[159] *Genendo*, 485 F.3d at 963 n. 3.
[160] United States v. Kaybel, 430 F.2d 1346 (3d Cir. 1970).
[161] *Id*. at 1347.
[162] *Id*.
[163] Brief of Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *6.
[164] *Id*. at *16.

VI. IMPLICATIONS OF THE SEVENTH CIRCUIT'S HOLDING

A. Packaging Concerns and Health Considerations

The FDCA was put in place to protect consumers from the inherent dangers accompanying the drug production process. Both the district court and Seventh Circuit were correctly concerned that imported Lipitor came from an unapproved packaging facility in Brazil. As the Seventh Circuit noted, there was no way of knowing the conditions under which the imported Lipitor was originally packaged and no way of later correcting any of these deficiencies at a repacking facility such as Phil & Kathy's.[165]

The FDCA takes these packaging considerations into account in various places. For instance, under § 351(a)(2)(A), a drug will be considered adulterated "if it has been prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health . . . ." These same concerns with packaging are reflected in numerous other places throughout the Act.[166]

Could these packaging provisions have acted as a check on the behavior of parties such as Genendo and Phil & Kathy's? Consider a hypothetical situation the same as ours here. The Lipitor is manufactured at an FDA-approved facility, but packaged at a facility in Brazil that is not FDA-approved, and instead of being seized at the border, the drugs enter the United States and are successfully repackaged at Phil & Kathy's. According to Genendo's argument, the imported Lipitor—and "any other similarly manufactured, packaged, labeled, and *unadulterated* drugs Genendo would import in the future"—would not be unapproved new drugs or misbranded because they are exempt from the labeling and packaging requirements of the

[165] *Genendo*, 485 F.3d at 964.

[166] *See e.g.*, 21 U.S.C. §351(a)(2)(B) (2000) (stating that a drug that is adulterated if the method of its packing does not conform to good manufacturing practices).

FDCA while on their way to Phil & Kathy's.[167] This argument assumes that the drugs are unadulterated, claiming immunity from being unapproved new drugs nor misbranded. However, if the drugs were packaged in Brazil under insanitary conditions, they are by definition adulterated and subject to seizure.[168] This is true without relying upon a statutory construction of § 353 that prohibits any importation of drugs that are not fully compliant with an NDA. The argument that the drugs are unapproved new drugs becomes moot.

Conversely, if the drugs packaged in Brazil are not exposed to insanitary conditions, they are not adulterated.[169] However, they would still fail to comply with the NDA because they were packaged in a different packaging facility, the labels are not in English, and the expiration period is different.[170] Thus, under the current statutory interpretation, they would be unapproved new drugs subject to seizure.[171] But what is the harm to the consumer in this case? None of the concerns with unsafe drugs resulting from insanitary packaging would come into play.[172] This would then allow parties such as Genendo to import drugs lawfully into the United States for distribution, after a repackaging facility such as Phil & Kathy's ensures that all of the proper labels, expiration dates, and other relevant information are placed on the drugs. Consumers would benefit by gaining access to another source to obtain safe and effective medication with full and accurate disclosures.

Finally, in the situation that the imported drugs were manufactured in an unapproved manufacturing facility, Genendo's

[167] Brief of Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *5 (emphasis added).

[168] 21 U.S.C. § 351(a)(2)(A) (2000)

[169] *Id*.

[170] United States v. 1500 90-Tablet Bottles, 384 F. Supp. 2d 1205, 1212 (N.D. Ill. 2005), *aff'd sub nom.* United States v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. 2007).

[171] *Genendo*, 485 F.3d at 963–64.

[172] *Id*. at 964.

own argument admits that such drugs are unapproved new drugs subject to seizure.[173]

B. Does Genendo *Foreclose All Parallel Imports?*

The Seventh Circuit's interpretation of the statute effectively prevents the majority of parallel imports. Any drug that a company such as Genendo wants to import will have to be purchased after it has been manufactured and packaged at an NDA- approved, and thus FDA-approved, facility. In the present case, this would leave Genendo with only the possibility of buying Lipitor from Frieburg, Germany or Vega Baja, Puerto Rico and not Sao Paulo, Brazil.[174] The probable reason the Brazilian facility is not an FDA-approved packaging facility[175] is because the drugs being packaged there are intended for distribution abroad. Pfizer has no reason to go through a rigorous FDA inspection for approval of its Brazilian facility if they do not plan for those drugs to enter the United States. This begs the question as to why Pfizer would even allow Genendo to purchase the Lipitor in Brazil. It clearly is not in Pfizer's interests to have that Lipitor sold in the United States or else the company would be doing that itself.

Meanwhile, if Genendo is limited to purchasing drugs manufactured and packaged at an FDA-approved facility, it will have to ensure that the only deviations from the NDA are those listed in the § 353 exemption.[176] This could be a hefty task, especially without access to the company's manufacturing and packaging information. It is easy to see how the transaction costs quickly rise in such a situation making it unfeasible for someone other than the drug's own

[173] Brief for Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *12.

[174] *Genendo*, 485 F.3d at 961.

[175] *Id*.

[176] *Id*. at 963. Again, those listed exemptions "relate to the requirement that the package contain the name and address of the manufacturer or distributor, a statement of the quantity of the contents, the established name of the drug, active and inactive ingredients, and adequate warnings and directions for use." *Id*.

manufacturer to import the drug into the United States. Thus, the parallel import is effectively prohibited.

If this is the result Congress intended, it could have drafted the original statute accordingly. Congress has demonstrated that it is capable of drafting such a section to prevent certain types of imports when it drafted § 381. That section prohibits anyone other than the manufacturer from re-importing into the United States drugs originally manufactured within the United States but shipped abroad for distribution.[177] In that same regard, Congress could have responded with later legislation accomplishing this goal.

This brings to the forefront the question of why has Congress not yet acted to explicitly declare parallel imports either legal or illegal? The cynical answer is that Congress is unduly influenced by the pharmaceutical lobby, whose interest it is to block the passage of a statute explicitly allowing parallel imports.[178] The pharmaceutical lobby maintains more than 600 lobbyists, more than one lobbyist for each member of Congress.[179] These lobbyists spent $435 million in Washington from 1996 to 2003, and doled out almost fifty-eight million dollars in contributions.[180]

Despite the presence of this strong lobby, it is clear that something needs to be done by Congress. In its first argument to the court, Genendo stated that parallel imports would have a cost saving result for American consumers[181]and much of American public echo this sentiment.[182] There are also those on the other side of the argument who take the view that such imports will result in minimal savings for American consumers.[183] Both sides of the argument have some merit, but it is Congress' job to arrive at a conclusion. An unbiased report

[177] 21 U.S.C. § 381(d) (2006).

[178] Barlett, supra note 4, at 1, 3.

[179] *Id*.

[180] *Id*.

[181] Brief of Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *i.

[182] *See, e.g.*, HHS TASK FORCE, *supra* note 16, at 65 (noting that consumers import drugs because they believe save money by buying outside of the United States).

[183] Danzon, *supra* note 11; HHS TASK FORCE, *supra* note 16, at XI, XIII.

would greatly assist Congress in this task. The process will have to be transparent so that it can be ensured neither the pharmaceutical lobby nor any "pro-import" group can unfairly effect the outcome. Furthermore, the public needs to be educated; a greater understanding of the true benefits and downfalls of drug importation will help dispel many myths that currently exist[184] and help ensure that the public understands the final compromise reached by Congress.

However, while the debate in Congress goes on, many Americans will continue to import their drugs in other ways, such as through online pharmacies or by driving to Canada or Mexico, all the while facing the threat that the drugs they buy will be part of the twenty-five percent counterfeit or substandard drugs found in developed countries.[185] Consumers are in an impossible position – they must choose between not getting any drugs at all because they cannot afford them, or getting drugs from outside the United States and taking a chance of suffering adverse consequences if the drugs are not safe. Consumers should not have to face this risk. This defeats the whole purpose of Congress' attempt to protect consumers and ensure the safety of their drugs through the FDCA.[186]

In order to reduce the amount of American consumers forced to turn outside our borders for their drugs, the FDA inspection process at our borders needs report. The FDA is already overburdened with the usual load of imports it must inspect on a daily basis. In 2001 at a House Committee hearing, Representative Greenwood reported that in the course of one month U.S. Customs detained 16,000 shipments in the Los Angeles mail facility alone, yet only had time to inspect 1,900

[184] *See, e.g.*, Gracie Marie Turner, *Drug Importation Myths Debunked*, TRI-STATE MEDIA, June 20, 2007, http://www.tristate-media.com/articles/2007/06/20/warricknews/editorial/01drug.txt; Nina Owcharenko, *Debunking the Myths of Drug Importation*, THE HERITAGE FOUNDATION, July 20, 2004, http://www.heritage.org/Research/HealthCare/wm542.cfm. Note that the accuracy of these "myths" may also be questioned.

[185] PFIZER, CASE STUDY: COUNTERFEIT CONTENTS, http://www.pfizer.com/files/products/CounterfeitContents.pdf (last visited Nov. 28, 2007).

[186] *See supra* notes 47–53 and accompanying text.

of those shipments.[187] The other shipments continued on to their destinations without any FDA inspection.[188] The Department of Health and Human Services confirms the burden on the FDA, stating that the "FDA currently does not have sufficient resources to ensure adequate inspection of current levels and categories of personal shipments of prescription drugs entering the U.S."[189]

If parallel imports, like that in *Genendo*, are explicitly made legal, what can be done to improve this deficient inspection process? One step would be to follow the lead of Genendo. Genendo twice notified the government of its intention to import Lipitor into the United States after trying to obtain a declaratory judgment that its actions were legal.[190] This notification probably gave the government sufficient knowledge to seize the imported Lipitor in the first place.[191] Subsequent importers should be required to follow this practice. Putting the burden on the importer to notify the United States may help facilitate inspections and ensure the quality of drugs entering the country. Importers seeking to avoid inspection will of course not follow such protocol. However, the importers who do abide by such a procedure will be the legitimate ones and the burden on the FDA would thus be lightened and would allow them to devote more time to stopping rogue importers. A second necessity is that the FDA simply needs more help. This is only going to come through additional funding from Congress. The inspection process cannot become more efficient with the current FDA importation field staff of 450 workers.[192] More people working on inspections means that more safe drugs will be properly allowed into the United States, and more importantly, more unsafe drugs will be stopped at our borders.

[187] PFIZER, CASE STUDY: BILLION DOLLAR BUSINESS, http://www.pfizer.com/files/products/BillionDollarBusiness.pdf (last visited Nov. 28, 2007).

[188] *Id*.

[189] HHS TASK FORCE, *supra* note 16, at XI.

[190] United States v. 1500 90-Tablet Bottles, 384 F. Supp. 2d 1205, 1210 (N.D. Ill. 2005).

[191] Brief of Appellant, Genendo Pharm. N.V., *Genendo*, 485 F.3d 958 (No. 03 C 6495), 2006 WL 498561, at *3.

[192] HHS TASK FORCE, *supra* note 16, at X.

CONCLUSION

The facts of *Genendo*[193] cast an interesting light over the on-going debate over how to lower prescription drug prices. The court's holding in *Genendo* was correct under the facts before it. It was unclear whether the imported Lipitor had in fact been originally packaged under sanitary conditions. The court erred on the side of safety. However, in arriving at this holding, the court's statutory interpretation of § 353 reduced opportunities for the importation of safe drugs. The result is that U.S. consumers will not benefit from a safe and inexpensive alternative drug source and may be forced to turn once again to drastic measures in order to save money on drug purchases. The court's attempt to promote the safety and welfare of American prescription drug consumers thus has the opposite intended effect: consumers are forced to weigh the choice of having no drugs at all, or gambling that far cheaper drugs purchased abroad or on black markets will be safe and effective. This certainly was not the goal of the court in issuing its decision, and it certainly is not a decision American consumers should have to make.

This is not an easy issue to resolve. Few consumers would question the requirement that the manufacturing and packaging plants be inspected and approved. The rigorous approval process is why consumers feel safe in using the drugs they receive in the United States.[194] However, few consumers would also question the need to lower the costs of prescription drugs. How does Congress balance the consumer need for cheap, effective prescription drugs with the enormous research and development costs pharmaceutical companies must somehow recoup?

American consumers are not waiting around for Congress to answer this question. They will continue importing drugs from abroad

[193] 485 F.3d 958.

[194] KAISER FAMILY FOUND., KAISER HEALTH POLL REPORT: VIEWS ON PRESCRIPTION DRUG SAFETY (Feb. 2005), *available at* http://www.kff.org/healthpollreport/feb_2005/3.cfm (noting that Eighty percent of the population feels at least "somewhat" comfortable with the safety of prescription drugs they purchase).

until congressional action is taken. By going out on their own and purchasing potentially counterfeit or substandard drugs, American consumers undermine Congress' goal of providing safe and effective drugs through the FDCA. Congress needs to specifically address the import issue in order to curtail this growing problem. This will require Congress to stand fast in the face of the powerful pharmaceutical lobby, which has a strong interest in maintaining the status quo. To ensure that it does not appear to be catering to the pharmaceutical lobby, Congress needs to be unbiased and as transparent as possible in the process of making a decision.

Congress also needs to ensure that better mechanisms be put in place to ensure that counterfeit and substandard drugs are not entering the United States, lawfully or not. Congress must ensure that the health of the majority of Americans who depend on prescription drugs on a daily basis is not jeopardized.[195] As part of this, the FDA inspection process needs to become more efficient. More inspections need to take place at our borders. This will require an increase in the number of FDA staff performing inspections, which in turn will require increased FDA funding. As more packages detained by the FDA are checked, the safety and efficiency goals of the FDCA are more fully served. These are legitimate but difficult policy issues that need to be addressed in the very near future.

[195] *See* KAISER FAMILY FOUND., *supra* note 1.